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| EXAMINER |
|---|
| HELMS, LARRY RONALD |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1642 | |

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16

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/855,632 | REITER ET AL. | |
| | Examiner | Art Unit | |
| | Larry R. Helms | 1642 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *04 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *87-93* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *87-93* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election without traverse of Group I, claim 1 which is canceled and newly added claims 87-93 are added to the invention of Group I originally presented in Paper No. 17 is acknowledged.

2. Claims 87-93 are pending and under examination.

### *Specification*

3. The disclosure is objected to because of the following informalities:

a. The first line of the specification should be updated to indicate the U.S. Patent numbers for applications 09/251835, 09/203939, 09/038,261, and 09/318503.

b. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed, for example, Antibodies to PSCA.

c. The Brief Description of the Drawings, pages 6-18, is incomplete as it lacks a separate description for the Figures. The Brief Description of the Drawings need to be amended so that Figures recite separate descriptions for each view that match the labels for the Drawings. Also any reference to the figures in the specification needs to be amended accordingly.

d. Although this application appears to be in sequence compliance all sequences listed in the application should have a SEQ ID NO. For example the

sequences on page 30, line 26, page 38 and page 66 need to have SEQ ID Nos for the sequences.

e. The address of the ATCC on page 28, line 3 needs to be updated. The new address is: 10801 University Boulevard, Manassas, VA 20110-2209.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 88 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 88 is indefinite for reciting "extracellular domain of PSCA of SEQ ID NO:2" because the exact meaning of the term is not clear. It is not clear which region of SEQ ID NO:2 is the extracellular domain. SEQ ID NO:2 is 123 amino acids long and it is not clear which of the 123 amino acids encompass the extracellular domain. The specification discloses the "extracellular domain" as any portion of the PSCA protein that is exterior to the plasma membrane of the cell (see page 24, lines 17-21). This definition does not define the regions of the protein which is exterior to the membrane.

***Double Patenting***

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 87-93 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,258,939 in view of Laus et al (U.S. Patent 6,194,152). The claims in the instant application are drawn to monoclonal antibodies to PSCA of SEQ ID NO:2 or portions of SEQ ID NO:2 wherein the antibody is a human, chimeric of Fab fragment and the hybridoma which produces the monoclonal antibody. The claims in US Patent 6,258,939 are drawn to specific antibodies that bind to SEQ ID NO:2 at residues 2 to 50, 46-109, and 85-123 and the hybridoma that produces such. The claims in the patent are to a species of antibodies and it would be obvious to obtain further antibodies to SEQ ID NO:2 which is a prostate stem cell antigen. The patent 6,258,939 does not claim Fab fragments, chimeric or humanized antibodies . These deficiencies are made up for in the teachings of Laus. Laus et al teach antibodies to prostate tumor cells and the antibodies can be Fab, chimeric or humanized (see column 23-26). It would have

been obvious to produce human, chimeric, of fragments of a monoclonal antibody to PSCA of Reiter et al as taught by Laus et al.

One of skill in the art would have been motivated and had a reasonable expectation of success to have produced human, chimeric, of fragments of a monoclonal antibody to PSCA of Reiter et al as taught by Laus et al because Reiter claims monoclonal antibodies to PSCA which is a prostate antigen and Laus et al teach fragments and chimeric and human antibodies to prostate antigens. Thus it would have been obvious to produce a chimeric, human, and fragments of the antibody of Reiter et al.

Claims 87-93 are directed to an invention not patentably distinct from claims 1-3 of commonly assigned 6,258,939. Specifically, see above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned 6,258,939, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 37 CFR 1.78(c) and 35 U.S.C. 132 to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Application for Patent or Patent to Another with Earlier Filing Date, Application Being Examined Filed on or After 11/29/00 or Filed Before 11/29/00 and Voluntarily Published under 35 U.S.C. 122(b)

> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

8. Claims 87, 88, 90, 92 are rejected under 35 U.S.C. 102(e) as being anticipated by Au-Young (U.S. Patent 5,856,136, filed 7/96).

The claims recite a monoclonal antibody to SEQ ID NO:2 wherein the antibody binds the extracellular domain of SEQ ID NO:2, the antibody is a chimeric antibody, and the antibody is a Fab fragment. For this rejection the phrase "extracellular domain" is being interpreted to mean any region of SEQ ID NO:2.

Au-Young et al teach antibodies to SEQ ID NO:2 (SEQ ID NO:2 of Au-Young is identical to SEQ ID NO:2 of the instant application, see SEQ ID NO:4 where nucleotide 465 can be "S" which in the IUPAC system is either C or G and this codon encodes ALA which is at position 94 in SEQ ID NO:2 of the instant application). Au-Young et al also teach the antibodies can be Fab and chimeric (see column 14, lines 10-59). Since the antibodies of Au-Young bind SEQ ID NO:2 it would be inherent that the antibodies would bind the extracellular domain which is SEQ ID NO:2.

### *Claim Rejections - 35 USC § 103*

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 87-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Au-Young et al (U.S. Patent 5,856,136, filed 7/96) as applied to claim87-88, 90, 92 above, and further in view of Green et al Nature Genetics 7:13-21, 1994).

Claims 87-88, 90, 92 have been described supra. Claims 89, 91 and 93 recite wherein the antibody is a human antibody, the antibody binds residues 2-50, 85-123, 46-109, and other recited regions of SEQ ID NO:2, and a hybridoma that produces an antibody to SEQ ID NO:2.

Au-young has been described supra. Au-Young also teach antibodies compositions are useful for the treatment or prevention of conditions associated with the presence or expression of the antigen (column 2, lines 59-63). Au-Young also teach antibodies can be made to "a portion of the amino acid sequence of the natural protein and may contain the entire amino acid sequence Of[or] a small naturally occurring molecules." (Column 14, lines 1-4). Au-Young teach production of antibodies by

determining regions of high immunogenicity and analysis to select epitopes such as those near the C-terminus or in hydrophilic regions as shown in Figure 5 (see column 28, lines 27-38). Au-Young does not teach human antibodies. This deficiency is made up for in the teachings of Green et al.

Green et al teach human monoclonal antibodies and the antibodies can be made using any antigen (see entire document).

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to have produced a human antibody to SEQ ID NO:2 of Au-Young in view of the teachings of Green et al.

One of ordinary skill in the art would have been motivated to and had a reasonable expectation of success to have produced a human antibody to SEQ ID NO:2 of Au-Young in view of the teachings of Green et al because Au-young teach antibodies compositions are useful for the treatment or prevention of conditions associated with the presence or expression of the antigen (column 2, lines 59-63) and it would have been obvious to produce human antibodies for treatment in humans in view of the teachings of Green et al which teach any antigen can be used to immunize the mouse to produce fully human immunoglobulins.

In addition, it would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made that the antibodies of Au-Young would bind to regions recited in claim 91 because Au-young teach antibodies to residues of 15 amino acids that are in regions of high immunogenicity based on the hydrophobic plot (see column 28, lines 27-49).

Although Au-Young does not specifically teach a hybridoma, it would have been obvious that monoclonal antibodies are produced from hybridoma cells and Au-Young teach the human B-cell hybridoma technique (see column 14, lines 22-32).

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

***Conclusion***

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

13. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the

Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242.

Respectfully,

Larry R. Helms Ph.D.

703-306-5879